5. 510(k) Summary of Safety and Effectiveness

MAR 5 2013

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared: February 27th 2012

The assigned 510(k) number is: _____

5-1. Applicant:

Fournitures Hospitalières industrie
6 Rue Nobel, Z.I. de Kernévez
29000 QUIMPER - FRANCE
Tel: (+33) 2.98.55.68.95
Fax: (+33) 2.98.53.42.13

5-2. Company Contact: Franck HUNT, General Manager
Tel: (+33) 2.98.55.68.95

5-3. Product :

Trade name: **CoLS® Fixation System**

Common name: Fixation screw and non absorbable surgical suture

Classification: Class II
Product code: MBI Smooth or threaded metallic bone fixation fastener
Regulation: 21 CFR 888.3040

5-4. Predicate/ Legally Marketed Device:

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	TLS® Fixation System
510 (K):	K080974

5-5. Device Description:

The **CoLS® Fixation System** is composed of the following elements:

- **The CoLS® tendon anchoring screw**, implantable device, used for the fixation of the CoLS® tendon anchoring tape to the bone.
- **The CoLS® tendon anchoring tape**, it is a non absorbable surgical suture, used for the ACL and PCL reconstruction, to which the tendon graft is attached.

This implantable tendon anchoring tape is used with accessories non implantable: tape support, passing wire and scalpel blade.

The CoLS® Fixation System is provided sterile and it is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

5-6. Indications for Use/ Intended Use:

As stated in the Indications for Use section and on the product related labeling (instructions for use and commercial documents):

The **CoLS® Fixation System** is designed for the fixation of tendons graft to the femur and tibia during orthopedic surgical procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

This is the same intended use as previously cleared for the TLS® Fixation System K080974

The intended use of the medical device, as described in its labeling, has not changed as a result of the modification
Therefore, no changes to the labels or instructions for use have occurred. We simply add another package to the currently existing.

5-7. Comparison of Technological Characteristics:

The CoLS® tendon anchoring screw and the CoLS® tendon anchoring tape have the same intended use and substantial similar indications for use as the predicate device.
- made out of the same material: titanium alloy and polyethylene terephtalate.
- have the same design.
- use the same operating principle,
- have the same method of sterilization: Gamma radiation.

5-8. Performances:

Tests were performed to compare the tensile strength on the Fixation System and also the biocompatibility of the final finished material. After the tests were completed, it was determined that the Fixation System performances were substantially equivalent to the selected predicate device.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

5-9. Substantial Equivalence:

The modified CoLS® Fixation System has the following similarities to the predicate device previously cleared 510(k):
- the same indication for use
- the same material
- the same design
- the same operating principle,
- the same sterilization method: Gamma radiation.

In summary, the CoLS® Fixation System described in this submission is substantially equivalent to the predicate device TLS® Fixation System.

5-10. Conclusion:

Following the examination of all the above mentioned information, we believe that the CoLS® Fixation System is substantially equivalent to the selected predicate device in terms of intended use, material, design, operating principle, sterilization, performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 5, 2013

Fournitures Hospitalières Industrie
% Mr. Franck Hunt
General Manager
6 Rue Nobel, Z.I. de Kernévez
29000 Quimper – France

Re: K120740
Trade/Device Name: CoLS® Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: February 19, 2013
Received: February 25, 2013

Dear Mr. Hunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin H. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K120740

Device Name:

CoLS® Fixation System
This device is composed of the following elements:
- The CoLS® tendon anchoring screw
- The CoLS® tendon anchoring tape

Indications for Use:

The **CoLS® Fixation System** is designed for the fixation of tendons graft to the femur and tibia during orthopedic surgical procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

Prescription Use: __**Yes**__ (Part 21 CFR 801 Subpart D)

AND/OR

Over the counter Use: ___**No**____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page __ of ___

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices